REMARKS

Status of the Claims

Claims 1-72 are currently pending. Claims 1-22 and 31-72 were rejected, while claims 24-30 were withdrawn from further consideration by the examiner as being drawn to a non-elected invention. Claims 1, 21, 31, 39, 45, 50, 60 and 68 have been amended, and claims 2-11, 13-20, 35-35, 43, 49, 56-57 and 66 have been cancelled without prejudice or disclaimer.

Support for the amendment of claim 1 is found in the specification, *inter alia*, on page 10, paragraph **[0038]**; pages 11-12, paragraph **[0044]**; page 12, paragraph **[0047]**; and original claims 5, 11 and 17. Claim 21 has been amended to change the dependency. Claims 31, 39, 45, 50, 60, and 68 have been amended to be dependent upon claim 1. Claim 45 was also amended to delete a hyphen at the Examiner's suggestion. Thus, no new matter has been added by way of these amendments.

Upon entry of the amendment, claims 1, 12, 21-34, 37-42, 44-48, 50-55, 58-65 and 67-72 will be pending. Entry of the amendment and reconsideration in view of the following comments is respectfully requested.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Sequence Rules Compliance

The Examiner objected to Applicant's newly submitted sequence listing submitted in the paper of January 11, 2007 asserting that the sequence of SEQ ID NO: 4 is different than that which previously existed and is thus considered new matter. The Examiner further stated that Applicant's submitted paper copy of the sequence listing does not appear to match the computer

readable copy of applicants sequence listing, specifically pointing to the sequence of SEQ ID NO: 4. Applicants respectfully traverse this objection.

The sequence identification listing originally filed February 28, 2005 was incorrect. The original sequence identification listing erroneously repeated the sequence of SEQ ID NO:2 for SEQ ID NO:4 rather than including the correct sequence for SEQ ID NO:4, as shown at page 13, paragraph **[0050]** of the specification as filed. The sequence identification listing provided in the paper of January 11, 2007 merely replaced the incorrect sequence for SEQ ID NO:4 with that sequence provided in the specification at page 13, paragraph **[0050]**. SEQ ID NO:4 as submitted in the sequence identification listing of January 11, 2007 is thus fully supported by the instant specification and does not constitute new matter.

Furthermore, the paper copy of the substitute sequence listing was compared to the CRF from the substitute sequence listing. The two are identical. A correct statement to that effect was filed on January 11, 2007.

Accordingly, entry of the substitute Sequence Listing submitted on January 11, 2007 into the above-captioned case, and withdrawal of the objection are respectfully requested.

Claim Objections

Claim 7 and 45 are objected to for various informalities.

Claim 7 was objected to as not being further limiting to claim 1. Claim 7 has been cancelled, and this rejection is now moot.

Claim 45 was objected to for reciting "A-kit for." As suggested by the Examiner, the hyphen has been removed. As such, Applicant submits that this objection should be withdrawn.

Applicant thanks the Examiner for his attention to these details. Should the Examiner object to any further informalities, he is requested to telephone the undersigned.

Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-10, 12-22 and 31-72 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner stated that the specification provides the 3'(2'), 5'-bisphosphate nucleotidase comprising the amino acid sequence of SEQ ID NO: 2 and methods of its use, but does not describe additional representative species of these enzymes or methods of use of said enzymes by any identifying structural characteristics or properties other than the activity, for which no predictability of structure is apparent. Applicants respectfully traverse this rejection.

The written description requirement "may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure" and compliance with the requirement "is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" See *Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, USPQ 65 USPQ2d 1385 (Fed. Cir. 2003); *Enzo Biochem, Inc. v Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). Quoting from the Patent Office's Written Description Requirement Guidelines, the Federal Circuit in *Enzo* stated that "the PTO has determined that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Written Description Requirements Guidelines, 66 Fed. Reg. 1099, 1106 (January 5, 2001) (emphasis added); *Enzo* at 1324.

Without acquiescence to the rejections and in the interest of expediting prosecution, Applicants have amended claim 1 to recite that the chimeric protein has the enzymatic activity of an nucleotidase, the leader sequence comprises the amino acid sequences set forth in SEQ ID NO:1, the nucleotidase comprises the amino acid sequence set forth in SEQ ID NO:2, and a third peptidyl

fragment comprises the amino acid sequence set forth in SEQ ID NO:3. In view of the claim amendment, Applicant respectfully submits that written description is satisfied by functional characteristics coupled with a known or a disclosed correlation between function and structure. The claims as amended recite the chimeric protein comprising specific sequences with a known function. Applicants respectfully submit that claims as amended comply with the written description requirement.

In view of the above, Applicant respectfully requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1-1 0, 12-22 and 31 are rejected, as allegedly not being enabling for the scope of the claims. The Examiner states that the specification, while being enabling for a 3'(2'),5'-bisphosphate nucleotidase comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any chimeric protein comprising any 3'(2'),5'-bisphosphate nucleotidase and any method of use of said 3'(2'),5'-bisphosphate nucleotidase comprising assessing the consumption of PAP or formation of AMP or Pi.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). MPEP § 2164.01. Experimentation is not considered undue, even if extensive, if it is routine or if the specification provides reasonable guidance regarding the direction of experimentation – time and difficulty are not determinative of undue experimentation if the experimentation is routine. *See PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996); *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-7; *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). The fact that experimentation may

be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112, is satisfied." *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970). MPEP § 2164.01(b) (emphasis added).

In order to make an enablement rejection, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). *See also* MPEP §2164.04, 8th ed., rev. 5, Aug. 2006, page 2100-187.

Without acquiescence to the rejections and in the interest of expediting prosecution, Applicants have amended claim 1 to recite that recite that chimeric protein has the enzymatic activity of an nucleotidase, the leader sequence comprises the amino acid sequences set forth in SEQ ID NO:1, the nucleotidase comprises the amino acid sequence set forth in SEQ ID NO:2, and a third peptidyl fragment comprises the amino acid sequence set forth in SEQ ID NO:3. Applicants respectfully submit that claims as amended are enabled. One skilled in the art can make and use the chimeric protein comprising the specific sequences as recited in the claims as amended without undue experimentation in view of the ample guidance provided in the specification. Methods for assaying the enzymatic activity of a nucleotidase are known in the art and described in the specification. *See, e.g.*, pages 10-11, paragraphs **[0040]-[0043]**. The specification also teaches methods of using the chimeric protein for assaying for sodium and lithium ions in a sample. *See,*

e.g., pages 15-26, paragraphs **[0057]-[0110]**; and Examples. Thus, Applicants respectfully submit that claims as amended are enabled.

In view of the above, Applicant respectfully requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Gil-Mascarell

Claims 1, 2, 6, 7, 10, 12, 31, 32, 37, 38, 39, 40, 45, 50, 60 and 63 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Gil-Mascarell *et al.* (Plant J., Vol 17, pp 373-383, 1999).

The legal standard for anticipation under 35 U.S.C. § 102 is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002). To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. *In re Paulson*, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (citing *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

Applicants have amended claim 1 include the sequences previously recited in claims 5, 11, and 17. Gil-Mascarell was not asserted against any of these claims, and as such, Gil-Mascarell does not teach each and every limitation of claim 1 – or any of the dependent claims – as amended.

Since Gil-Mascarell does not teach each and every limitation of the claims, it fails to meets the strict identity standard for anticipation under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that this anticipation rejection under 35 U.S.C. § 102(b) should be withdrawn.

Albert et al.

Claims 1, 6, 7, 8 and 9-12 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Albert et al. (J. Mol. Biol. 295:927-938, 2000, See IDS).

The legal standard for anticipation is discussed above and is incorporated herein.

Applicants have amended claim 1 to include the sequences previously recited in claims 5, 11, and 17. Albert *et al.* was not asserted against claims 5 and 17, and as such, Albert *et al.* does not teach each and every limitation of claim 1 – or any of the dependent claims – as amended.

Since Albert *et al.* does not teach each and every limitation of the claims, it fails to meets the strict identity standard for anticipation under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that this anticipation rejection under 35 U.S.C. § 102(b) should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 466992001100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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